

### **REMARKS**

Applicants submit this amendment in response to the Notice of Non-Responsive Amendment. It is Applicants' understanding that the previous amendment, dated August 6, 2010, has been entered and will be reviewed with the present amendment. Accordingly, Applicants are not resubmitting the "Claims" and "Remarks" section of the response dated August 6, 2010. Applicants respectfully request that this response be reviewed with the "Claims" and "Remarks" sections submitted with the response dated August 6, 2010.

#### **Election of Species**

In response to the Office Communication, Applicants elect with traverse, pancreatic cancer as the species of cancer and paclitaxel as the species of chemotherapeutic agent. Claims 36-63 and 67-77 read on the elected species. Applicants have included claim 56 in the list of claims that the elected species read on because pancreatic cancer may metastasize to the liver.

Applicants traverse the election of species because the search for one species of cancer or chemotherapeutic agent will give results that are relevant to the search for the other species of cancers or chemotherapeutic agents. Accordingly, the search for the different species of cancers and chemotherapeutic agents are related.

It is Applicants' understanding that the Examiner intends to begin by searching the elected species and will continue searching until art is found or until a generic claim is found allowable. Applicants also point out that when a generic claim is found to be allowable, the withdrawn claims which depend from or include the limitations of the allowed claim must be rejoined and fully examined for patentability (MPEP 809).

#### **Obviousness-Type Double Patenting**

A. Claims 36-63 and 67-70 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9, 11, 14, 18, and 20 of copending Application 11/018,574.

Applicants point out that Application 11/018,574 has now issued as U.S. Patent 7,794,747 ('747). In contrast to the claims of the present application which are directed to methods of treating a human patient comprising administering a cationic liposomal composition

comprising paclitaxel, the claims in '747 are directed to novel and unobvious methods of making a cationic liposomal composition comprising a taxane. The claims of the present application and of '747 are patentably distinct inventions.

Applicants respectfully point out that *In re Ochiai* is not relevant to the present obviousness-type double patenting rejection. The Court in *Ochiai* reviewed the issue of whether a known method of making a novel and nonobvious product is patentable and concluded that a known method of making a product is patentable if the product is novel and nonobvious. As discussed above, the claims in '747 and the claims in the present applications are directed to patentably distinct novel and nonobvious methods of making and using cationic liposomal compositions comprising taxane and paclitaxel, respectively. The claims of '747 are based in part on Applicants finding of an improved method for making a cationic liposomal composition comprising taxane, while in the claims of the present application are based in part on Applicants finding of a novel and nonobvious method of using cationic liposomal compositions comprising paclitaxel to treat human patients.

Moreover, if the claims of '747 and the currently pending claims were present in the same pending application, the Patent Office would have separated them into two different groups of inventions and requested an election of one of the inventions for search and examination, and Applicants would have elected an invention for search and examination in the pending application and filed a divisional application to pursue the second invention. Applicants respectfully point out that according to Section 804 of the MPEP, a double patenting rejection is not permitted where the claimed subject matter is presented in a divisional application as a result of a restriction requirement. Here, the claims, directed to methods of making a cationic liposomal composition comprising a taxane and a method of treating a human patient comprising administering a cationic liposomal composition comprising a paclitaxel, are in separate applications because they are not directed to the same invention and they are patentably distinct inventions. Applicants respectfully request withdrawal of the rejection.

B. Claims 36-63 and 67-70 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 13, 16, and 22 of copending Application 12/300,448.

Applicants respectfully point out that the claims in Application 12/300,448 are directed to methods of inhibiting cartilage and/or bone erosion which are patentably distinct from the claims of the present application.

Moreover, Applicants respectfully point out that this is a provisional rejection between two copending applications. MPEP 804 (I)(B)(1) (page 800-17) states,

If the “provisional” nonstatutory obviousness-type double patenting rejections are the only rejections remaining in those applications, the examiner should withdraw the obviousness-type double patenting rejection in the earlier filed application, thereby permitting that application to issue without need of a terminal disclaimer.

The present application is the earlier filed application. Thus, if this is the remaining rejection in the present application, Applicants respectfully request withdrawal of this rejection in accordance with MPEP 804 (I)(B)(1).

C. Claims 36-63 and 67-70 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 5, and 9 of copending Application 12/308,748.

Applicants respectfully point out that the claims in Application 12/308,748 are directed to methods of treating an ocular neovascularization disease which are patentably distinct from the claims of the present application.

Moreover, Applicants respectfully point out that this is a provisional rejection between two copending applications. MPEP 804 (I)(B)(1) (page 800-17) states,

If the “provisional” nonstatutory obviousness-type double patenting rejections are the only rejections remaining in those applications, the examiner should withdraw the obviousness-type double patenting rejection in the earlier filed application, thereby permitting that application to issue without need of a terminal disclaimer.

The present application is the earlier filed application. Thus, if this is the remaining rejection in the present application, Applicants respectfully request withdrawal of this rejection in accordance with MPEP 804 (I)(B)(1).

### Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request entry of the amendments,

reconsideration, and the timely allowance of the pending claims. A favorable action is awaited. Should an interview be helpful to further prosecution of this application, the Examiner is invited to telephone the undersigned.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 13-3250. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,  
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